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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,483	12/05/2001	Igor Yu Goryshin	960296.97541	3618

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09/22/2004

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EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/22/2004

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/007,483

Applicant(s)

GORYSHIN ET AL.

Examiner

Nancy T. Vogel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, drawn to a polynucleotide comprising first and second transposase-interacting inverted repeat sequence pairs, classified in class 536, subclasses 23.1 and 24.1.
- II. Claims 9-11, drawn to a method for producing a gene fusion library using transposable polynucleotides and copies of a first target nucleic acid molecule and a transposase, classified in class 435, subclass 473.
- III. Claim 12 and 16, drawn to a method for deleting a portion of a chromosome of a host cell, and a chromosome lacking a portion of nucleic acid and comprising a pair of non-identical transposase-interacting sequences, classified in class 435, subclass 473 and class 536, subclass 23.1.
- IV. Claim 13, drawn to a method for cloning a portion of a chromosome of a host cell, classified in class 435, subclass 91.41.
- V. Claim 14 and 17, drawn to a method for inserting a preselected polynucleotide sequence insert into a chromosome of a host cell, and the chromosome containing an inserted portion flanked by a pair of non-identical transposase-interacting sequences, classified in class 435, subclass 473 and 536, subclass 23.1.

- VI. Claim 15, drawn to a polynucleotide fusion product between portions of a first and second genes encoding a polypeptide fusion, linked by a pair of non-identical transposase-interacting sequences, classified in class 536, subclass 23.4.
- VII. Claim 18, drawn to a self replicating nucleic acid molecule comprising a pair of non-identical transposase-interacting sequences flanking a portion of a chromosome and an origin of replication, classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

The products of Groups I, VI and VII, are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups (each of which can be isolated from cells or organisms, made synthetically, and/or are self-replicating without the need for the isolated products of the other groups). Therefore, the inventions of the groups are capable of supporting separate patents.

Inventions of Groups II-V are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups II-V comprise steps which are not required for or present in the methods of the other groups: mixing together copies of a transposable polynucleotide comprising a first and second transposase-interacting inverted repeat sequence pairs, with copies of a first target nucleic acid molecule that comprises a first polypeptide-encoding gene a first origin of replication and a selectable marker gene, and with a first transposase that

binds to an interacts with the first sequence pair, to produce a first transposition products, introducing the first transposition products into host cells; selecting host cells that comprise first transposition products wherein the first polypeptide –encoding gene sequence is disrupted by the transposable polynucleotide; mixing the transposition products from the selected host cells and a second target nucleic acid molecule that comprises a second gene sequence, a second origin of replication and a third sequence that confers selectability upon a host cell, and a second transposase that binds to an interacts with the second sequence pair, to produce second transposition products; introducing the second transposition products into host cells; selecting host cells that comprise second transposition products comprising fusions between the first and second gene sequence (Group II); introducing in a host cell a synaptic complex comprising a first transposase and a transposable polynucleotide comprising first and second transposase-interacting inverted repeat pairs, members of the first pair flanking members of the second sequence pair, further comprising between the member of the second inverted repeat sequence pair a first sequence for conferring selectability and a polynucleotide that encodes a second transposase that binds to an interacts with the second sequence pair and still further comprising, between a first adjacent pair of distinct inverted repeat sequences, a second sequence for conferring selectability; selecting host cells in which the transposable polynucleotide has integrated into the chromosome, inducing expression of the second transposase in the host cells, and screening to isolate cells in which a portion of the chromosome is deleted (Group III); screening to isolate cells in which a portion of the chromosome is cloned onto a self-

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replicating nucleic acid molecule that comprises an origin of replication (Group IV); and screening to isolate cells in which a preselected polynucleotide sequence insert is inserted into the chromosome and a second sequence for conferring selectability upon a host cell is lost from the chromosome (Group V). The end result of the methods are different: the production of a gene fusion library (Group II); the production of host cells having deletions in the chromosome (Group III); the production of a cloned portion of the chromosome (Group IV); the production of host cells having polynucleotides inserted into the chromosome (Group V). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Inventions of Group VI and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as by in vitro biosynthesis.

Inventions of Group VII and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different

process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as by in vitro biosynthesis.

Inventions of Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group I can be used in the methods of Groups III-V.

Except for the specific relationships described above, the invention of Groups I and VI and Groups II-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). In the instant case the different products of Groups I and VI are not used in or made by the methods of Groups II-V.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Further more, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. Therefore, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

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dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

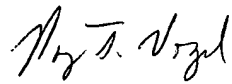
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nancy T. Vogel, Ph.D.
Patent Examiner